

AMENDED IN ASSEMBLY APRIL 13, 2009

AMENDED IN ASSEMBLY APRIL 2, 2009

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 1458

Introduced by Assembly Member Davis

February 27, 2009

An act to add Article 7 (commencing with Section 111657.10) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to public ~~health~~: *health*.

LEGISLATIVE COUNSEL'S DIGEST

AB 1458, as amended, Davis. Drugs: adverse effects: reporting.

Existing law establishes various programs for the prevention of disease and the promotion of health to be administered by the State Department of Public Health, including, but not limited to, a program for the licensing and regulation of health facilities and clinics. Existing law requires certain health facilities to report adverse events, as defined, relating to patient care. Existing law requires the department to regulate the manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act. A violation of these provisions is a crime.

This bill would require clinics, health facilities, and health professionals to report serious adverse drug events to the federal Food and Drug Administration and would exempt violations from related criminal provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) The federal Food and Drug Administration (FDA) operates
4 a voluntary reporting system for adverse drug reactions known as
5 the MedWatch system.

6 (b) The FDA currently estimates that only 10 percent of the
7 adverse drug reactions or events that occur each year are reported
8 to the FDA.

9 (c) Given the prevalence of pharmaceuticals and their use for
10 treatment of hundreds of chronic diseases and conditions, and
11 given recent highly publicized instances of commonly used
12 prescription drugs being taken off the market due to safety concerns
13 that were discovered after the drugs were approved for use, the
14 systematic underreporting of adverse drug events represents a
15 serious public health problem.

16 (d) Requiring licensed health professionals and health facilities
17 to report adverse drug events to the FDA would increase the
18 amount of data available to the FDA about adverse drug reactions,
19 thereby enabling the FDA to discern problems with drugs that arise
20 after they are approved and to take action to protect the public
21 health in a more timely manner.

22 SEC. 2. Article 7 (commencing with Section 111657.10) is
23 added to Chapter 6 of Part 5 of Division 104 of the Health and
24 Safety Code, to read:

25
26 Article 7. Adverse Event Reporting
27

28 111657.10. (a) A licensed health professional, including, but
29 not limited to, a physician and surgeon, dentist, or pharmacist, a
30 health facility as defined in Section 1250, or a clinic as defined
31 under Chapter 1 (commencing with Section 1200), shall report all
32 suspected serious adverse drug events that are spontaneously
33 discovered or observed in medical practice to MedWatch, the drug
34 safety information and adverse event reporting program operated
35 by the federal Food and Drug Administration (FDA).

36 (b) For purposes of this section, serious adverse drug events
37 shall include adverse health outcomes involving patients that result
38 in death, life-threatening conditions, hospitalization, disability,

1 congenital anomaly, or that require intervention to prevent
2 permanent impairment or damage.

3 (c) Any health professional, health facility, or clinic that is
4 required to report an adverse drug event pursuant to this section
5 ~~shall do so in addition to reporting requirements pursuant to Section~~
6 ~~1279, and~~ shall use the FDA 3500 Voluntary form developed by
7 the FDA for MedWatch.

8 111657.15. A licensed health professional, health facility, or
9 clinic that violates any provision of this article shall not be subject
10 to the penalties and remedies outlined in Chapter 8 (commencing
11 with Section 111825) ~~or any other provision of law~~. Nothing in
12 this section affects otherwise existing duties, rights, or remedies
13 under the law.